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Titanium materials for surgical implant applications Part 1 : Unalloyed titanium

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare, and Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from the Japanese Society for Biomaterials (JSB), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on **ISO 5832-2 : 1999 *Implants for surgery—Metallic materials—Part 2 : Unalloyed titanium*** for the purposes of making easy to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

JIS T 7401 series consist of the following six parts with the general title of *Titanium materials for surgical implant applications*.

Part 1 : Unalloyed titanium

Part 2 : Wrought titanium 6-aluminium 4-vanadium alloy

Part 3 : Wrought titanium 6-aluminium 2-niobium 1-tantalum alloy

Part 4 : Wrought titanium 15-zirconium 4-niobium 4-tantalum alloy

Part 5 : Wrought titanium 6-aluminium 7-niobium alloy

Part 6 : Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Titanium materials for surgical implant applications

Part 1 : Unalloyed titanium

Introduction This Japanese Industrial Standard has been prepared based on the first edition of **ISO 5832-2** *Implants for surgery—Metallic materials—Part 2 : Unalloyed titanium* published in 1999 without modifying the technical contents, but some items which not specified in the original International Standard are added.

The portions underlined with dots are the matters not stated in the said International Standard.

1 Scope This Standard specifies unalloyed titanium for use in the manufacture of surgical implants, especially its chemical composition, metallic properties, mechanical properties and internal properties. It is required to use unalloyed titanium clinically after investigating the safety corresponding to the environment where implants are used. The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this Standard.

Remarks : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

ISO 5832-2 : 1999 *Implants for surgery—Metallic materials—Part 2 : Unalloyed titanium* (MOD)

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

- JIS H 0321 *General rules for inspection of non-ferrous metal materials*
- JIS H 1610 *Titanium and titanium alloys—Sampling methods*
- JIS H 1611 *Titanium and titanium alloys—General rules for chemical analysis*
- JIS H 1612 *Methods for determination of nitrogen in titanium and titanium alloys*
- JIS H 1614 *Methods for determination of iron in titanium and titanium alloys*
- JIS H 1617 *Methods for determination of carbon in titanium and titanium alloys*
- JIS H 1619 *Methods for determination of hydrogen in titanium and titanium alloys*
- JIS H 1620 *Methods for determination of oxygen in titanium and titanium alloys*
- JIS H 1630 *Method for atomic emission spectrometric analysis of titanium*
- JIS T 0301 *Testing method for biocompatibility of implantable metals using cultured cells*
- JIS T 0302 *Testing method for corrosion resistance of metallic biomaterials by anodic polarization measurement*